IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
COLUMBIA DIVISION

Pacira Biosciences, Inc., Plaintiff, vs. Nephron Sterile Compounding Center, LLC; W. Bradley Worthington; MMOSA, LLC; and Hutchison Health, LLC, Defendants.	)	C/A No. 3:23-5552-CMC **ORDER GRANTING IN PART AND DENYING IN PART MOTIONS TO DISMISS**

Plaintiff Pacira Biosciences, Inc. ("Pacira") brought this action against Nephron Pharmaceuticals Corporation on November 1, 2023. An amended complaint was filed on February 5, 2024, that changed Defendants to Nephron Sterile Compounding Center, LLC ("Nephron"); W. Bradley Worthington; MMOSA, LLC; and Hutchison Health, LLC (the "Worthington Defendants")[1] (collectively, "Defendants"). Pacira alleges Defendants engaged in false and misleading advertising practices that "have directly harmed Pacira and, in turn, have potentially put unsuspecting patients in harm's way." Amend. Comp. at 2, ECF No. 25. Pacira brings this action pursuant to the Lanham Act, 15 U.S.C. §§ 1051, *et seq*. Defendants have separately moved to dismiss pursuant to Fed. R. Civ. P. 12(b)(6).

I. FACTS AND PROCEDURAL HISTORY

Pacira alleges it markets and manufactures non-opioid pain management products, including EXPAREL®. According to Pacira, EXPAREL® is composed of bupivacaine suspended in multivesicular liposomes. The product is injected at a surgical site during or shortly after surgery

[1]Defendant Worthington is the sole member of MMOSA, LLC and Hutchison Health, LLC.

to manage and reduce post-surgical pain. Pacira reports EXPAREL® has been tested and approved by the Food and Drug Administration (the "FDA") and has been used to treat over ten million patients across the United States. *Id.* at 3.

Pacira asserts Nephron operates a compounding pharmacy and has partnered with Worthington to produce, market, and distribute a compounded drug product called "BKK." BKK is comprised of ketorolac, ketamine, and bupivacaine in a syringe for combined use. *Id.* at 6. Pacira also alleges Nephron manufactures, markets, and sells "RKK," a compounded drug consisting of syringes of ketorolac, ketamine, and ropivacaine for combined use. *Id.* at 6-7. Compounded drug products are not approved by the FDA, but may be manufactured and sold to the public if they meet the requirements of 21 U.S.C. § 353b.[2] Section 353b(a), entitled "Outsourcing Facilities," provides, in part:

> (a) In general
>
> Sections 352(f)(1) [Directions for use and warnings on label], 355 [New drugs], and 360eee-1 [Requirements] of this title shall not apply to a drug compounded by or under the direct supervision of a licensed pharmacist in a facility that elects to register as an outsourcing facility if each of the following conditions is met:
>
> (1) Registration and reporting
>
> The drug is compounded in an outsourcing facility that is in compliance with the requirements of subsection (b).
>
> (2) Bulk drug substances
>
> The drug is compounded in an outsourcing facility that does not compound using bulk drug substances (as defined in section 207.3(a)(4) of title 21, Code of Federal Regulations (or any successor regulation)), unless–

[2]Section 353b codifies Section 503B of the Drug Quality and Security Act, PL 113-54, Nov. 27, 2013, 127 Stat 587, as a segment of the Federal Food, Drug, and Cosmetic Act ("FDCA"). Section 353b also is known as the "Section 503B exemption."

> (A)(i) the bulk drug substance appears on a list established by the Secretary identifying bulk drug substances for which there is a clinical need, by–
>
> (I) publishing a notice in the Federal Register proposing bulk drug substances to be included on the list, including the rationale for such proposal;
>
> (II) providing a period of not less than 60 calendar days for comment on the notice; and
>
> (III) publishing a notice in the Federal Register designating bulk drug substances for inclusion on the list; or
>
> (ii) the drug compounded from such bulk drug substance appears on the drug shortage list in effect under section 356e of this title at the time of compounding, distribution, and dispensing[.]

Pacira alleges Defendants' production of BKK and RKK does not satisfy the requirements of § 353b because (1) BKK and RKK do not appear on the FDA's drug shortage list, and (2) the bulk drug substances from which BKK and RKK are made do not appear on the FDA's list of bulk drug substances for which there is a clinical need. ECF No. 25 at 10. *See* 21 U.S.C. § 353b(a)(2)(A)(i-ii). According to Pacira, "An outsourcing facility that compounds using 'bulk drug substances' cannot satisfy the 503B exemption simply by combining FDA-approved drugs or 'bulk drug substances' that are included on either list, or at varying dosages, to sell an unapproved compounded drug. . . . In other words, a compounder cannot meet the 503B exemption just by combining drugs or bulk substances on the lists to create a new combined product that is not on these lists." ECF No. 25 at 10-11.

Pacira's legal challenges to Defendants' products are not asserted under § 353b, however. This is because private enforcement of § 353b is barred: "[A]ll such proceedings for the enforcement, or to restrain violations of [the FDCA] shall be by and in the name of the United States." 21 U.S.C. § 337(a). Rather, Pacira seeks redress pursuant to the false advertising

provisions of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B). Section 1125(a)(1)(B) provides, in relevant part:

> (a) Civil action
>
> (1) Any person who, on or in connection with any goods or services, or any container for goods, uses in commerce any word, term, name, symbol, or device, or any combination thereof, or any false designation of origin, false or misleading description of fact, or false or misleading representation of fact, which–
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> . . . .
>
> (B) in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities,
>
> shall be liable in a civil action by any person who believes that he or she is or is likely to be damaged by such act.

According to Pacira, Defendants "have engaged in a sustained campaign to promote their drug cocktail products as safe and effective opioid alternatives through demonstrably false and misleading advertisements – including blatantly false statements that their drugs are safer and more effective than EXPAREL®[.]" ECF No. 25 at 1-2. Pacira contends Defendants have made misleading statements claiming or implying BKK and RKK compounds have been approved by the FDA and/or subjected to clinical studies and trials. *Id.* at 7. Pacira states Defendants knowingly induced healthcare providers to purchase the BKK and RKK products on the providers' mistaken belief these compounds are FDA approved and/or otherwise comply with the FDCA, to the detriment of their patients.

Pacira asserts two grounds for relief: As to all Defendants, Pacira claims false and misleading advertising and promotion of the BKK product under 15 U.S.C. § 1125(a)(1)(B) (Count I); and, as to Nephron only, false and misleading advertising and promotion of the RKK product

under 15 U.S.C. § 1125(a)(1)(B) (Count II).[3] Pacira alleges it has been directly injured by Defendants' actions in the form of lost business, market share, sales, revenue, and profits, among other "serious and ongoing harms." *Id.* at 8. Pacira seeks monetary relief in the form of an award of Defendants' profits; disgorgement of Defendants' profits by which Defendants allegedly have been unjustly enriched; actual damages, costs, reasonable attorney's fees; and pre-judgment, post-judgment, and other interest on monetary damages.

This matter is before the court on motion to dismiss the amended complaint filed by Nephron on March 4, 2024. ECF No. 41. Pacira filed a response in opposition on April 1, 2024, ECF No. 50, to which Nephron filed a reply on April 22, 2024, ECF No. 51. The Worthington Defendants filed a motion to dismiss on March 18, 2024. ECF No. 44. Pacira filed a response in opposition on April 22, 2024, ECF No. 52, to which the Worthington Defendants filed a reply on May 3, 2024, ECF No. 54.

II. LEGAL STANDARD

Defendants move to dismiss pursuant to Fed. R. Civ. P. 12(b)(b). To survive a Rule 12(b)(6) motion, "[f]actual allegations must be enough to raise a right to relief above the speculative level." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). The "complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Twombly*, 550 U.S. at 570). A claim is facially plausible when the factual content allows the court to reasonably infer that the defendant is liable for the

[3]Pacira states, on information and belief, Worthington is the creator of BKK and holds the intellectual property rights to the BKK product. Pacira claims Worthington neither has rights to nor developed RKK, but reserves the right to assert claims against Worthington should contrary facts come to light during discovery.

misconduct alleged. *Id.* When considering a motion to dismiss, the court must accept as true all of the factual allegations contained in the complaint. *Erickson v. Pardus*, 551 U.S. 89, 94 (2007).

III. DISCUSSION

To prevail in a false advertising claim under 15 U.S.C. § 1125(a)(1)(B), a plaintiff must show:

> (1) the defendant made a false or misleading description of fact or representation of fact in a commercial advertisement about his own or another's product; (2) the misrepresentation is material, in that it is likely to influence the purchasing decision; (3) the misrepresentation actually deceives or has the tendency to deceive a substantial segment of its audience; (4) the defendant placed the false or misleading statement in interstate commerce; and (5) the plaintiff has been or is likely to be injured as a result of the misrepresentation, either by direct diversion of sales or by a lessening of goodwill associated with its products.

PBM Prod., LLC v. Mead Johnson & Co., 639 F.3d 111, 120 (4th Cir. 2011) (quoting *Scotts Co. v. United Indus. Corp.*, 315 F.3d 264, 272 (4th Cir. 2002)).

Further,

> "the contested statement or representation must be either false on its face or, although literally true, likely to mislead and to confuse consumers given the merchandising context." *C.B. Fleet Co. v. SmithKline Beecham Consumer Healthcare, L.P.*, 131 F.3d 430, 434 (4th Cir.1997). "Where the advertisement is literally false, a violation may be established without evidence of consumer deception." *Cashmere & Camel Hair Mfrs.*, 284 F.3d [302,] 311 [1st Cir. 2002)]. But if "a plaintiff's theory of recovery is premised upon a claim of implied falsehood, a plaintiff must demonstrate, by extrinsic evidence, that the challenged [advertisements] tend to mislead or confuse consumers." *Johnson & Johnson Merck Consumer Pharm. Co. v. Smithkline Beecham Corp.*, 960 F.2d 294, 297 (2d Cir.1992); *see also Abbott Labs. v. Mead Johnson & Co.*, 971 F.2d 6, 14 (7th Cir.1992) ("[A] court may find on its own that a statement is literally false, but, absent a literal falsehood, may find that a statement is impliedly misleading only if presented with evidence of actual consumer deception.").
>
> "In analyzing whether an advertisement . . . is literally false, a court must determine, first, the unambiguous claims made by the advertisement . . . , and second, whether those claims are false." *Scotts [Co. v. United Indust. Corp.*], 315 F.3d [264,] 274 [(4th Cir. 2002)] (quoting *Novartis Consumer Health v. Johnson & Johnson–Merck*

Consumer Pharmaceuticals, 290 F.3d 578, 586 (3d Cir.2002)). "A literally false message may be either explicit or conveyed by necessary implication when, considering the advertisement in its entirety, the audience would recognize the claim as readily as if it had been explicitly stated." *Id.*

Id.

A. Nephron's Motion to Dismiss Counts I and II

As to Count I, Pacira alleges the following false claims in violation of § 1125(a)(1)(B):

- **BKK is generic to or substitutable for EXPAREL®**. This claim is literally false or impliedly false because BKK, which is not FDA-approved, does not have technology causing the bupivacaine to be released over time, and does not provide pain relief for up to 72 hours.

- **BKK is FDA-approved.** This claim is false and misleading because the FDA has not approved BKK.

- **BKK is produced in an FDA-approved facility.** This claim is literally false and/or misleading because the FDA does not "approve" facilities.

- **BKK is compounded in compliance with Section 503B.** This claim is literally false and/or misleading because BKK does not satisfy the requirements of Section 503B.

- **BKK is compounded in a 503B-compliant outsourcing facility.** This claim is literally false and/or misleading because Nephron compounds drug products which do not comply with the requirements of Section 503B.

- **BKK "improves patient safety, satisfaction, recovery time, patient outcomes" and "patient experience."** These statements are false and/or misleading because they convey the impression that BKK is safe, effective, and superior to other FDA-approved drugs – such as EXPAREL®, [but] it is not.

- **BKK "reduces postoperative pain, complications, risk of readmission, length of stay, patient morbidity and mortality."** This claim is false and misleading because it conveys the impression that BKK is safe, effective, and superior to other FDA-approved drugs – such as EXPAREL®, [but] it is not.

- **BKK is more "efficacious for long term analgesia" and "post operative pain" than EXPAREL®**. These claims are literally false because they are

untrue. These claims are further misleading because they convey the false impression that BKK has undergone the same level of efficacy testing as FDA-approved EXPAREL® and/or has been proven to be "efficacious" through head-to-head comparative testing, when it has not.

- **EXPAREL® "DOES NOT DELIVER THE ANALGESIC AND ANTIEMETIC BENEFITS OF BKK."** This claim is literally false because it is untrue. This claim is further misleading because it conveys the false impression that BKK has undergone the same level of efficacy testing as FDA-approved EXPAREL® and/or has been proven to be more efficacious through head-to-head comparative testing, when it has not.

ECF No. 25 at 31-32.

As to Count II, Pacira asserts:

- **RKK is generic to or substitutable for EXPAREL®**. This claim is literally false or impliedly false because RKK, which is not FDA-approved, does not have technology causing the bupivacaine[4] to be released over time, and does not provide pain relief for up to 72 hours.

- **RKK is FDA-approved.** This claim is false and misleading because the FDA has not approved RKK.

- **RKK is produced in an FDA-approved facility.** This claim is literally false and/ or misleading because FDA does not "approve" facilities.

- **RKK is compounded in compliance with Section 503B.** This claim is literally false and/or misleading because RKK does not satisfy the requirements of Section 503B.

- **RKK is compounded in a 503B-compliant outsourcing facility.** This claim is literally false and/or misleading because Nephron compounds drug products which do not comply with the requirements of Section 503B.

- **RKK "[r]educes post-operative pain complications, risk of readmission, length of stay, patient morbidity and mortality," "[e]liminates opioid related adverse drug effects," and has "low reported incidents of nausea and vomiting."** These claims are false and/or misleading because they convey the impression that RKK is safe, effective, and superior to other FDA-approved drugs – such as EXPAREL®, [but] it is not.

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[4]The term "bupivacaine" appears to be a scrivener's error, as Count II relates to "ropivacaine."

- **RKK provides "improved value" over EXPAREL®**. This claim is literally false because it is untrue. This claim is further misleading because it conveys the false impression that RKK has undergone the same level of efficacy testing as FDA-approved EXPAREL® and/or has been proven to provide "improved value" through head-to-head comparative testing, when it has not.

ECF No. 25 at 33.

Nephron contends Pacira's complaint fails to state a claim under Rule 12(b)(6) because:

> (1) Pacira does not identify any false or misleading statements by Nephron including, without limitation, [statements] contained in a commercial advertisement regarding Nephron's own product, or Pacira's product, EXPAREL®; (2) the statements identified by Pacira in its Amended Complaint do not actually deceive or have a tendency to deceive a substantial segment of their audience; (3) any alleged deception was immaterial as Pacira fails to plausibly plead that it was likely to influence purchasing decisions; (4) Nephron did not cause the statements identified on the slides included in the Amended Complaint to enter interstate commerce; (5) Pacira fails to plead that it was actually damaged as a result of the purportedly false statements including through diversion of sales or the lessening of goodwill; and (6) Pacira's claim is preempted by the exclusive enforcement provision of the Federal Drug Control Act [*sic*] ("FDCA"), 21 U.S.C. § 337(a) ("all such proceedings for the enforcement, or to restrain violations of [the FDCA] shall be by and in the name of the United States.").

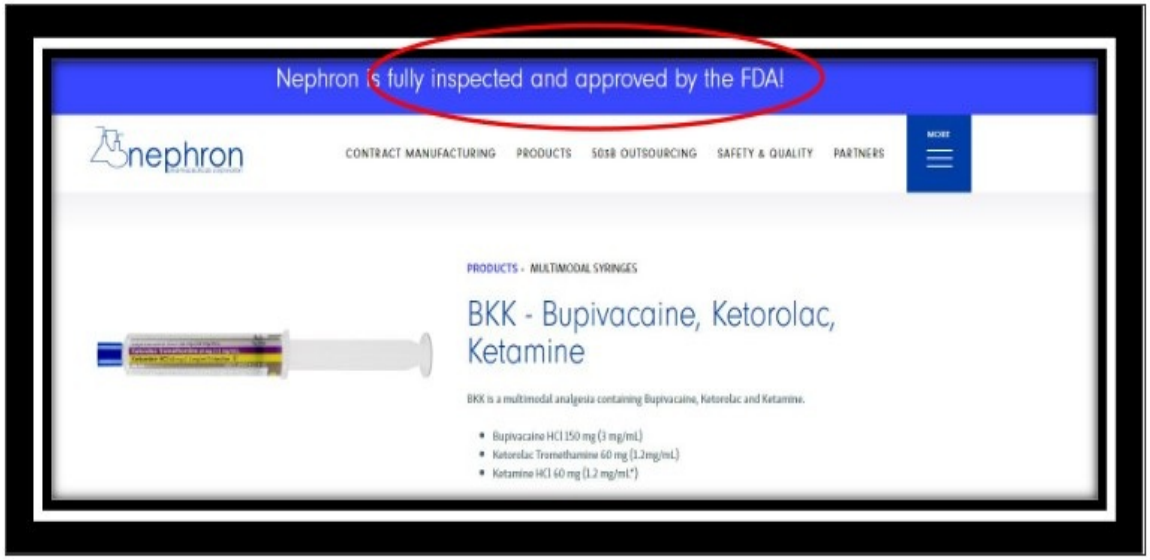
ECF No. 41-1 at 7-8.

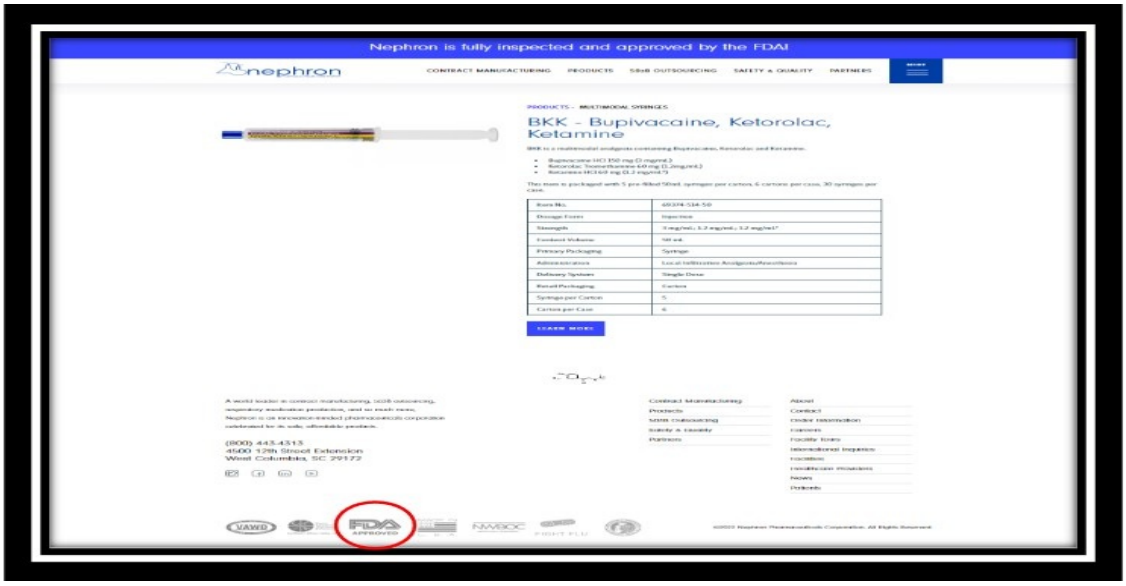
1. Whether Pacira plausibly alleges Nephron put forth literal or implied false statements of fact that are likely to mislead consumers.

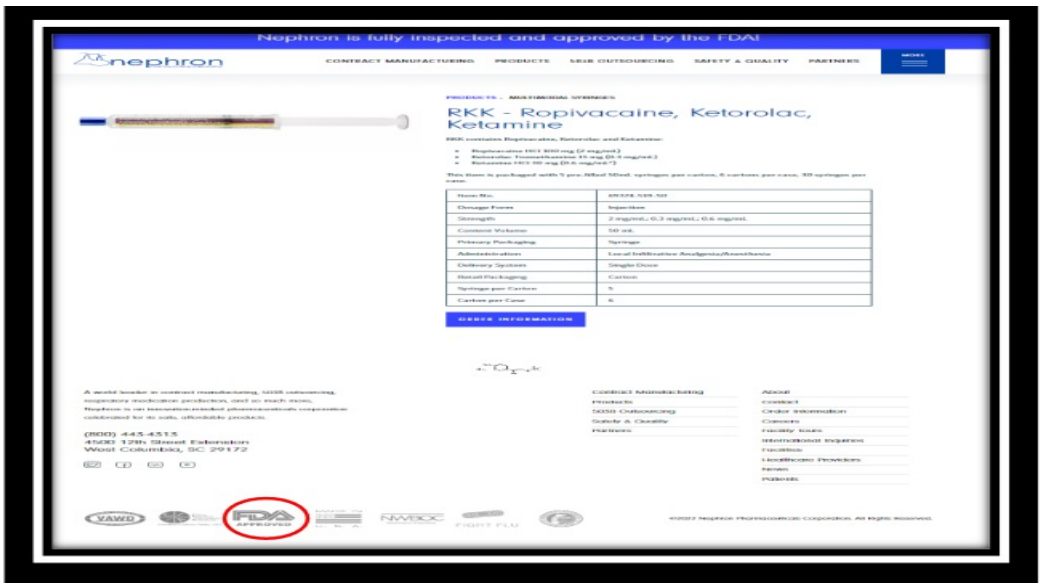
Nephron alleges Pacira's false advertising claims fall into three categories: (1) statements made on Nephron's advertising and product information website pages (the "Website Statements") that allegedly misrepresented BKK and RKK to be safe, effective, and FDA-approved; (2) statements made in two "cherry picked" slides contained within a larger slide deck presentation for hospitals and providers that allegedly implied BKK was generic to or substitutable for EXPAREL® (the "Presentation Statements"); and (3) statements contained in product overview materials (the

"Product Overview Materials") that referred to Nephron as a 503B outsourcing facility and allegedly misrepresented BKK and RKK to be safe, effective, and superior to other FDA-approved drugs, such as EXPAREL®.

a. The Website Statements. Pacira contends Nephron's website advertising falsely suggests the FDA has reviewed and approved BKK and RKK, and that the BKK and RKK products were produced in an FDA-approved facility.







According to Nephron, the "Nephron is fully inspected and approved by the FDA!" banner and "FDA APPROVED" logo at the foot of Nephron's website appeared in the same place on every page of Nephron's website, including its landing page. Nephron asserts the statements did not refer to BKK, RKK, or any other drug. Rather, considered in context, the banner and footer, which included other logos, such as "MADE IN U.S.A.," obviously reference only Nephron. Nephron also contends the banner and footer are not literally false because Nephron is, in fact, a registered 503B

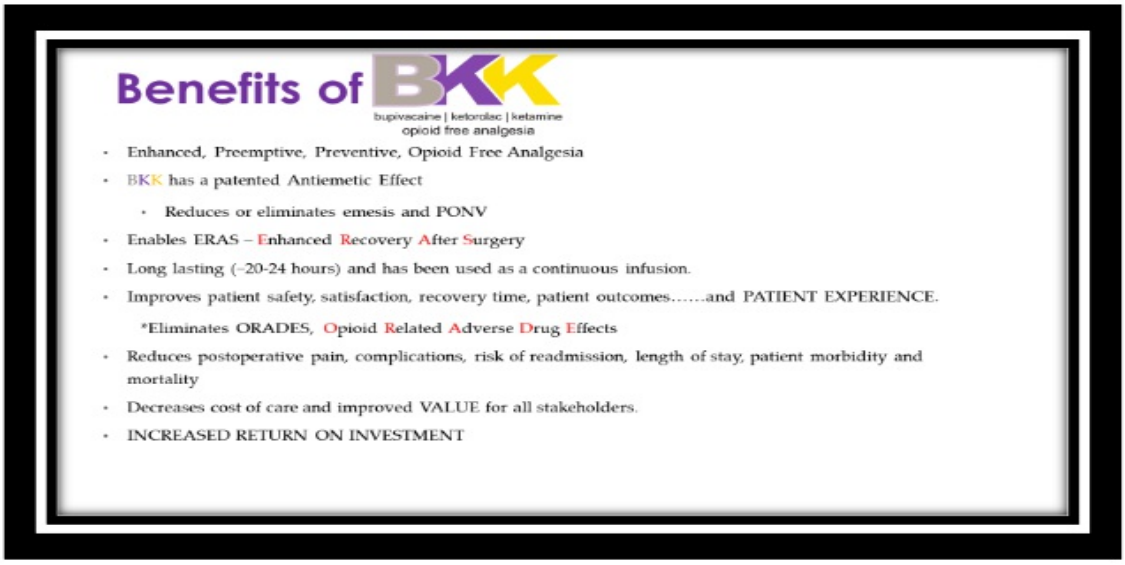
outsourcing facility both certified and regularly inspected by the FDA. Nephron states its drug compounding is done in compliance with the FDA's compounding program. In addition, Nephron contends Pacira's arguments do not support a finding of explicit misrepresentation, but, at most, implicit misrepresentation. Nephron submits courts consistently dismiss claims based on implicit representations of FDA approval.

In response, Pacira argues the statements set forth in the banner and footer convey the false impression Nephron's products are produced in an FDA-approved facility when, in fact, the FDA does not approve facilities. Pacira submits the web pages convey the expressly false representation BKK and RKK have been reviewed and approved by the FDA and have been assessed to meet the FDA's standards of safety and efficacy. Pacira asserts a customer looking for information related to BKK and RKK will not necessarily peruse every page on Nephron's website to notice the banner and footer repeat on each page. In addition, Pacira argues the footer's other logos – such as "MADE IN U.S.A." – lead the consumer to falsely believe the footer's logos apply to Nephron's products, and not its facilities.

"False advertising claims based on allegations of implied government approval have not been allowed, for 'the law does not impute representations of government approval . . . in the absence of explicit claims.'" *Impact Applications, Inc. v Concussion Mgmt., LLC*, Case No.: GJH-19-3108, 2021 WL 978823, at *6 (D. Md. Mar. 16, 2021) (quoting *Merck & Co., Inc. v. Mediplan Health Consulting, Inc.*, 425 F. Supp. 2d 402, 417 (S.D.N.Y. 2006)). The Website Statements do not explicitly state BKK and RKK have received FDA approval. Nor do the Website Statements explicitly state BKK and RKK were produced in a FDA-approved facility. Nephron's motion to dismiss is granted as to the Website Statements regarding FDA approval and BKK and RKK being

produced in a FDA-approved facility.

b. The Presentation Statements. Pacira alleges Defendants have made false claims to hospitals and providers in presentation and other marketing materials about the efficacy, safety, and superiority of BKK and RKK.



Nephron first contends Pacira's presentation allegations regarding BKK fail because Nephron did not make the Presentation Statements referenced in the amended complaint. According to Nephron, the BKK slides cited in the amended complaint were part of a larger presentation made by Worthington. Nephron further contends Pacira fails to plead facts, as opposed to mere conclusory assertions, demonstrating any statement contained in the slides included in the amended complaint is literally false or likely to mislead consumers. Nephron states Pacira puts forth no extrinsic evidence to support its claim of falsity, and fails to suggest a client or prospective client was deceived. Further, Nephron argues Pacira alleges no facts showing BKK or RKK does not improve patient recovery time, reduce postoperative pain, or reduce length of stay. Nephron submits Pacira alleges no facts to support a finding either BKK or RKK does not reduce post-operative pain complications, risk of readmission, length of stay, patient morbidity and mortality, or that BKK does not lower the cost of care and provide improved value.

Pacira, in response, contends the Presentation Statements are attributable to Nephron because Nephron hired Worthington to create the slide show and conduct the presentations. In the amended complaint, Pacira alleges Worthington worked closely with Nephron to develop, market, and sell BKK. Pacira alleges Worthington "not only developed advertisements and marketing materials for BKK, but he also actively participated in sales pitches and other promotional events *nationwide* to sell" BKK. ECF No. 25 at 6. Taking Pacira's allegations as true, the court finds, for purposes of Nephron's motion to dismiss, Worthington's BKK sales activities are imputable to Nephron. *See, e.g., Crystal Ice Co. of Columbia, Inc. v. First Colonial Corp.*, 257 S.E.2d 496, 497 (S.C. 1979)(quoting 2A C.J.S. Agency § 52, p. 623).

Pacira submits, as with the Website Statements, Nephron falsely and misleadingly communicated in its Presentation Statements and other advertising materials "that BKK and RKK are FDA APPROVED." ECF No. 50 at 30. As discussed *supra*, none of the Presentation Statements or marketing materials relied on by Pacira explicitly maintains the FDA has approved BKK or RKK. Pacira fails to state a claim for relief based on alleged FDA approval in the Presentation Statements.

Pacira further contends it pointed to Nephron's "myriad false and misleading claims" in the amended complaint that, if proven, entitle Pacira to relief. Pacira cites to *Mylan Lab'y, Inc. v. Matkari*, 7 F.3d 1130 (4th Cir. 1993), a case also relied on by Nephron, in support of its argument. In *Mylan*, the Fourth Circuit held the plaintiff's claims the defendants falsely represented their drugs had been approved by the FDA failed because the plaintiff could point to no statement or representation in the defendants' advertising that declared proper FDA approval. Moreover, the Fourth Circuit held the very act of placing a drug on the market with standard package inserts often used for FDA-approved drugs did not falsely imply the drug had been approved by the FDA. 7 F.3d

at 1139. The Fourth Circuit also determined, however, a different count of the complaint alleged sufficient falsity to survive a motion to dismiss. In that count, the plaintiff alleged a defendant falsely represented its product was "bioequivalent to its innovator counterpart and other approved generic equivalents"; the product was "entitled to an AB rating" from the FDA; and the product was the "generic alternative" to the innovator drug. *Id.* at 1138. In support of those claims, Mylan alleged, among other things, approval had been obtained through fraud and the data for the bioequivalence studies had been "falsified" or was seriously "unreliable."

Similarly, Pacira alleges claims of improved patient safety, satisfaction, recovery time, outcomes, and patient experience are false and misleading. Pacira alleges claims of reduced postoperative pain, complications, risk of readmission, length of stay, and patient morbidity and mortality are false and misleading. With respect to a different slide referenced in the amended complaint, included below, Pacira alleges Nephron's advertising gives the false impression BKK and RKK are safe, effective, and superior to FDA-approved drugs such as EXPAREL®. According to Pacira, Nephron falsely advertised, offered for sale, and sold the BKK and RKK products as a generic of, substitutable for, or otherwise replacements for EXPAREL®. Pacira contends Nephron's superiority claims, including that BKK and RKK are more "efficacious for long term analgesia" and "post operative pain" than EXPAREL®, are literally false.

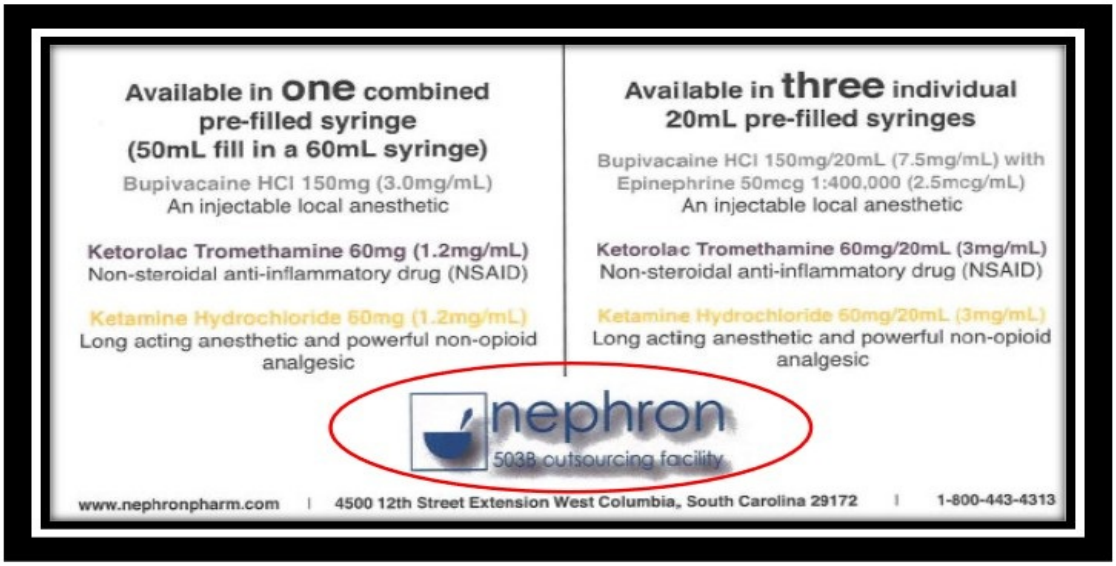
Nephron does not specifically address the "Competition" slide in its motion to dismiss.[5] Nephron states, however, Pacira's reliance on conclusory assertions lacking substantiation cannot support a literal falsity claim. In the amended complaint, Pacira alleges BKK and RKK are not generic to or substitutable for EXPAREL® because neither BKK nor RKK has technology causing the bupivacaine [or ropivacaine] to be released over time. Otherwise, Pacira simply alleges benefits attributed to BKK and RKK "are literally false because they are untrue." ECF No. 25 at 31-32, 33. Where the disputed statement is made baldly, with no assertion of test or study validation, its literal falsity may only be proven by proof that the favorable fact baldly asserted is false. *See C.B. Fleet Co., Inc. v. SmithKline Beecham Consumer Healthcare, L.P.*, 131 F.3d 430, 435 (4th Cir. 1997)(citing cases).

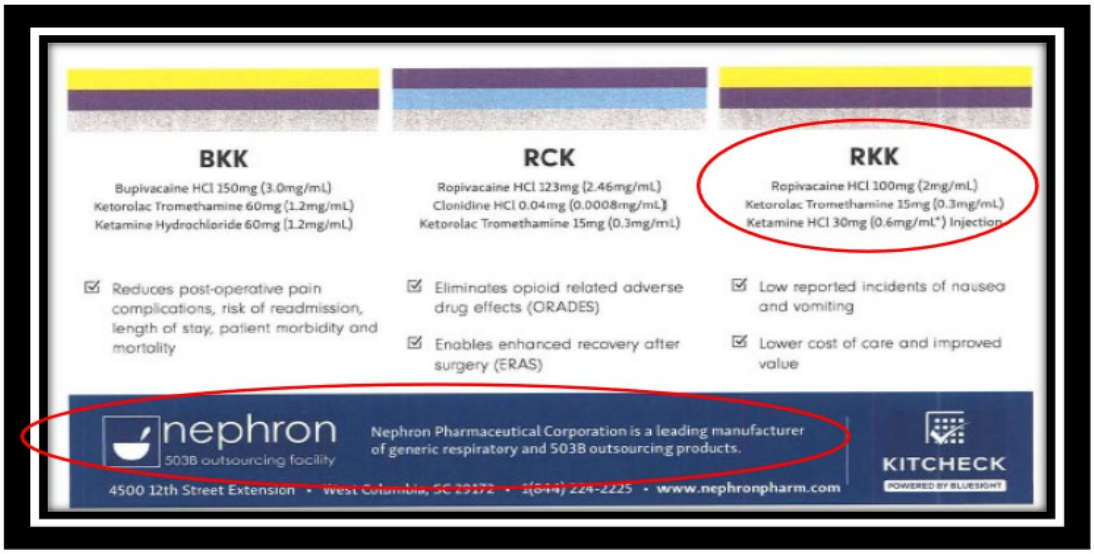
The essence of Pacira's complaint is that BKK and RKK are inferior products because they

[5] The "Competition" slide is included in the attachments to the motion to dismiss as part of Worthington's presentation. ECF No. 41-2 at 94.

have not been subjected to the FDA's rigorous testing standards. Certainly Pacira will be required to offer cogent evidence to support its contentions before a factfinder to the extent it asserts Nephron's statements are literally false. Nevertheless, the court concludes Pacira's allegations are adequate to withstand Nephron's motion to dismiss as to these and other unambiguous statements relating to the benefits of BKK and RKK and the superiority of these products as compared to EXPAREL®. Nephron's motion to dismiss is denied as to the Presentation Statements and other marketing materials in this regard.

c. The Product Overview Statements. Pacira contends the logo indicating Nephron is a 503B outsourcing facility conveys the false impression BKK and RKK products are produced by a 503B-compliant facility.





According to Nephron, the statement Nephron is a 503B outsourcing facility is true.

Pacira alleges in the complaint this statement is false and/or misleading because Nephron compounds drug products that do not comply with the requirements of § 353b; that is, the bulk substances – ketamine, bupivacaine, ketorolac, and ropivacaine – do not appear on a list for which there is a clinical need, and the BKK and RKK products compounded from ketamine, bupivacaine, ketorolac, and ropivacaine do not appear on the applicable drug shortage list.[6] As observed previously, Pacira alleges Nephron has combined drugs or bulk substances to create a new combined

[6]In support of its argument, Pacira points to ECF No. 41-2 at 9 and 41-2 at 31-33, which comprise Exhibits C and D to an affidavit appended to Nephron's motion to dismiss. Exhibit C is a Nomination List, which includes ketamine, bupivacaine, ketorolac, and ropivacaine as candidates for the Clinical Need List. Exhibit D is a Clinical Need List, which does not include ketamine, bupivacaine, ketorolac, and ropivacaine. Typically, a court will "not consider extrinsic evidence when evaluating the sufficiency of a complaint. However, [a court] may properly consider documents attached to a complaint or motion to dismiss 'so long as they are integral to the complaint and authentic.'" SOURCE.auction, LLC v. Farkas, Civil Action No. 3:17-CV-185-RJC-DCK, 2017 WL 7736155, at *3 (W.D.N.C. Nov. 3, 2017)(quoting *Anand v. Ocwen Loan Servicing, LLC*, 754 F3d 195, 198 (4th Cir. 2014)). The court will consider Exhibits C and D in its analysis.

product that has not been tested by the FDA.

Nephron's claim it is a 503B outsourcing facility, even if true, could falsely imply BKK and RKK satisfy the requirements of § 353b, if, indeed, they do not. Further, to prevail on a claim of implied falsity, Pacira must proffer extrinsic evidence the Product Overview Statements confused consumers regarding the safety and efficacy of BKK and RKK products. *See Scotts Co.*, 315 F.3d at 276. In its complaint, Pacira alleges:

> 152. On information and belief, healthcare providers and consumers have reasonably relied on Defendants' false and misleading statements when deciding to purchase BKK or RKK instead of EXPAREL®.
>
> 153. Upon information and belief, had healthcare providers known that Defendants' Unapproved Compounded Drug Cocktails neither received FDA approval nor complied with federal law, they would have never purchased and used them.
>
> 154. Further, on information and belief, had healthcare providers and consumers known that Defendants' efficacy and/or superiority claims related to their Unapproved Compounded Drug Cocktails were false and misleading, they would never have purchased and used Defendants' drugs.

ECF No. 25, 29-30.

Pacira argues Nephron's "advertising gives the false and misleading impression that BKK and RKK are efficacious *and* superior to Pacira's FDA-approved EXPAREL project[.]" ECF No. 50 at 32. According to Pacira, Nephron disseminated its statements to a relevant market of healthcare providers and sold thousands of units of BKK and RKK to providers and hospitals in the United States. The court concludes Pacira's allegations are adequate to withstand Nephron's motion to dismiss. Nephron's motion to dismiss is denied as to the Product Overview Statements.

2. Whether Pacira Plausibly Alleges Nephron Disseminated Its False Statements as Commercial Advertisements to the Purchasing Public. According to Pacira, Defendants distributed

and presented false and misleading marketing and promotional materials to healthcare providers and consumers to induce such providers and consumers to purchase BKK and RKK.

"The Supreme Court has identified three qualities of commercial speech: whether the message is economically motivated, promotes a specific product, and is an advertisement." *Handsome Brook Farm, LLC v. Humane Farm Animal Care, Inc.*, 700 F. App'x 251, 257 (4th Cir. 2017)(citing *Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60, 66-67 (1983)). Fourth Circuit precedent "allude[s] to yet another quality of commercial speech: whether the message is 'placed in a commercial context and [is] directed at the providing of services rather than toward an exchange of ideas.'" *Id.* (quoting *Greater Balt. Ctr. for Pregnancy Concerns, Inc. v. Mayor & City Council*, 721 F.3d 264, 286 (4th Cir. 2013)).

Nephron contends Pacira fails to define or allege a relevant market or to set forth any facts showing the Product Overview Statements were sufficiently disseminated by Nephron, or the Product Overview Statements were presented in connection with the sale, offering for sale, distribution, or advertising of BKK and RKK. Nephron states Pacira fails to offer any description of the identity or number of individuals who may have actually seen the Presentation Statements. Nephron also submits experienced healthcare providers would not be misled or confused about the FDA approval status of BKK or RKK by the information shown on the Product Overview Statements. Nephron concludes, "Pacira's complaint amounts to nothing more than an allegation that some hospitals and providers were presented with a less expensive option than EXPAREL® by a party other than Nephron, which option they may have chosen." ECF No. 41-1 at 29.

Pacira observes Nephron does not contest its presentation statements are commercial speech promoting its products that were provided to a relevant market – healthcare providers. The question

is whether the Product Overview Statements constitute advertising. Pacira merely states the "product overviews constitute commercial advertising." ECF No. 50 at 32.

In its amended complaint, Pacira alleges the Product Overview Statements were included in "marketing materials" and "advertisements." ECF No. 25 at 17, 25-26, 28. Pacira alleges:

> 148. On information and belief, Defendants have distributed and presented their false and misleading marketing and promotional materials to healthcare providers and consumers to induce such providers and consumers to purchase Defendants' Unapproved Compounded Drug Cocktails.
>
> 149. For example, on information and belief, Defendants have targeted healthcare providers and consumers using unsolicited promotional emails containing false and misleading claims about the Unapproved Compounded Drug Cocktails.
>
> 150. On information and belief, Defendants have also hosted informational sessions, meetings, and/or other events where they have distributed and/or presented false and misleading claims about the Unapproved Compounded Drug Cocktails directly to healthcare providers and consumers.

ECF No. 25 at 29.

While "information and belief" pleading can sometimes survive a motion to dismiss, a plaintiff must allege specific facts sufficient to support a claim. *Scott v. Experian Info. Sols, Inc.*, Case No. 18-CV-60178-ALTONAGA/Seltzer, 2018 WL 3360754, at *5 (S.D. Fla. June 29, 2018)(cited with approval in *Frazier v. Experian Info. Sols., Inc.*, CIVIL NO. JKB-18-0067, 2018 WL 3785131, at * 3 (D. Md. Aug. 9, 2018)). Accepting Pacira's allegations as true for purposes of the motion to dismiss, the court concludes Pacira has plausibly alleged Nephron's Presentation Statements and Product Overview Statements regarding its BKK and RKK products were offered for the purpose of inducing sales to a designated market. Although the Presentation Statements and Product Overview Statements may have encompassed an educational component, it would strain credulity to find Nephron did not intend to turn a profit convincing its target audience to purchase

BKK and RKK. Nephron's motion to dismiss is denied as to this issue.

3. Whether Pacira plausibly pleads injury caused by Nephron. Pacira contends it has suffered injuries in fact and actual damages as the result of Defendants' false representations that induced healthcare providers and consumers to purchase BKK and RKK rather than EXPAREL®.

Nephron argues Pacira "makes only vague and conclusory allegations, namely that 'Nephron has engaged in false and misleading advertising to lure providers to purchase its unlawful drugs instead of EXPAREL®, to Pacira's detriment' and 'Pacira has suffered injuries in fact and actual damages, including lost business, market share, sales, revenue, and profits.'" ECF No. 41-1 at 30 (quoting ECF No. 1, ¶¶ 118, 124). Indeed, the amended complaint provides: "As a direct and proximate result of Defendants' knowing and willful false and misleading statements, false advertising, and wrongful acts of unfair competition related to the BKK product, Pacira has suffered injuries in fact and actual damages, including lost business, market share, sales, revenue, and profits." ECF No. 25 at 32; *see also* ECF No. 25 at 33 (making same allegations regarding RKK).

Other courts have found similar allegations survive a motion to dismiss. *See, e.g., CBD Indus., LLC v. Majik Med., LLC*, CIVIL ACTION NO. 3:21-CV-069-RJC-DCK, 2022 WL 18893076, at *7 (W.D.N.C. Oct. 19, 2022 (holding sufficient a counterclaim allegation that "Defendant has been and continues to be unfairly economically damaged by the use of these unsubstantiated claims . . . and will continue to suffer . . . damage to its . . . goodwill."); *Geiger v. Abarca Fam., Inc.*, Civil Action No. 3:21cv771 (DJN–EWH), 2022 WL 4242838 (E.D. Va. July 29, 2022)(holding sufficient allegations "the modeling industry places a 'high degree of value on their good will and reputation,' and that being associated with the Club (with the implication that they are entertainers), or otherwise endorse the Club, 'substantially injures their careers' and 'deprives them

of income they are owed relating to the commercialization of their [i]mages'"); *ISK Biocides, Inc. v. Pallet Machinery Grp. Inc.*, Civil Action No. 3:21-cv-386, 2022 WL 122923, at *6 (E.D. Va. Jan. 12, 2022)(holding sufficient an allegation "[a]s a direct and proximate result of [the d]efendants' [misrepresentation], ISK has and will continue to suffer damage to its business, reputation, goodwill, and the loss of sales, profits, and customers").

The court concludes Pacira's amended complaint, when read as a whole, states a facially plausible claim that (1) Nephron developed BKK and RKK products in a manner contrary to FDA regulations; (2) Nephron falsely advertised BKK and RKK products to a target audience as safe, efficacious, and less expensive than EXPAREL®; and (3) Pacira suffered injury as a result. Nephron's motion to dismiss is denied as to this issue.

4. Whether Pacira's claim is precluded by the exclusive enforcement provision of the FDCA. Pacira asserts its claims under the Lanham Act.

Nephron contends Pacira's Lanham Act claims are precluded because adjudicating Pacira's complaint requires the court to decide whether, under the FDCA and its regulations, a violation has occurred. According to Nephron, the crux of Pacira's complaint is its allegation Nephron falsely advertised BKK and RKK as safe, effective, and approved by the FDA when they are not. Pacira rebuts Nephron's argument by contending the court need only confirm (1) neither BKK, RKK, nor the component bulk drug substances used by Nephron to compound BKK or RKK are on the FDA's Clinical Need List; and (2) neither BKK nor RKK are on the Drug Shortage List. Pacira asserts that, if both statements prove true, Nephron's statements claiming 503B compliance or exemption "will be unquestionably false and/or misleading." ECF No. 50 at 16.

In *Pom Wonderful LLC v. Coca-Cola Co.*, 573 U.S. 102, 106 (2014), the Court explained the

"intersection and complementarity" of the Lanham Act and the FDCA. The Court observed the "Lanham Act creates a cause of action for unfair competition through misleading advertising or labeling. Though in the end consumers also benefit from the Act's proper enforcement, the cause of action is for competitors, not consumers. . . . Competitors are within the class that may invoke the Lanham Act because they may suffer "an injury to a commercial interest in sales or business reputation proximately caused by [a] defendant's misrepresentations." *Id.* at 107. On the other hand, "[t]he FDCA statutory regime is designed primarily to protect the health and safety of the public at large." *Id.* at 108. To achieve this result, the "FDCA and its regulations provide the United States with nearly exclusive enforcement authority, including the authority to seek criminal sanctions in some circumstances. 21 U.S.C. §§ 333(a), 337." *Id.* at 109. Significantly,

> [t]he two statutes complement each other with respect to remedies in a more fundamental respect. Enforcement of the FDCA and the detailed prescriptions of its implementing regulations is largely committed to the FDA. The FDA, however, does not have the same perspective or expertise in assessing market dynamics that day-to-day competitors possess. Competitors who manufacture or distribute products have detailed knowledge regarding how consumers rely upon certain sales and marketing strategies. Their awareness of unfair competition practices may be far more immediate and accurate than that of agency rulemakers and regulators. Lanham Act suits draw upon this market expertise by empowering private parties to sue competitors to protect their interests on a case-by-case basis. By "serv[ing] a distinct compensatory function that may motivate injured persons to come forward," Lanham Act suits, to the extent they touch on the same subject matter as the FDCA, "provide incentives" for manufacturers to behave well. Allowing Lanham Act suits takes advantage of synergies among multiple methods of regulation. This is quite consistent with the congressional design to enact two different statutes, each with its own mechanisms to enhance the protection of competitors and consumers.

POM Wonderful, 573 U.S. at 115-16 (internal citations omitted).

The argument as framed by Pacira in its response to Nephron's motion to dismiss reasonably could be read as identifying wrongful conduct on the part of Nephron, i.e., using component bulk

drug substances in a prohibited manner. The court also notes perhaps Pacira was overzealous in describing BKK and RKK products in its complaint as "illegal," "unlawful," and as posing "significant risks to patient safety and health," ECF No. 25 at 6, 15, 23, 30, which terms could implicate the need for enforcement by the FDCA. Nevertheless, the gravamen of Pacira's allegations demonstrate Pacira's concern the allegedly false and misleading statements made by Nephron regarding BKK and RKK, as well as the lower price points at which these compounds are sold, have negatively impacted the profitability of Pacira's business. Nephron's motion to dismiss is denied as to this issue.

B. The Worthington Defendants' Motion to Dismiss Count I

The Worthington Defendants summarize their arguments as follows:

> Plaintiff's First Amended Complaint ("FAC") fails on three essential grounds: (1) Plaintiff fails to allege that Defendants Bradley Worthington ("Defendant Worthington"), MMOSA, LLC ("Defendant MMOSA"), or Hutchison Health, LLC ("Defendant Hutchison") engaged in or utilized false or fraudulent advertising related to Dr. Worthington's patented product; (2) Plaintiff fails to allege that any of the unnamed recipients of information about Dr. Worthington's product – all of whom Plaintiff identifies as providers and hospitals – were actually deceived or capable of being deceived; and (3) Plaintiff asks this Court to affirmatively find that Defendants violated the Food, Drug, and Cosmetics, Act ("FDCA") – a classic enforcement action in the exclusive authority of the Food and Drug Administration ("FDA"). See 21 U.S.C. § 337(a).

1. Whether Pacira fails to state allegations against MMOSA, LLC and Hutchison Health, LLC.

Pacira alleges, upon information and belief, Worthington is the sole member of MMOSA, LLC and Hutchinson Health, LLC. According to Pacira, Worthington assigned part or all of his rights in BKK to one or both of these entities.

The Worthington Defendants state that, other than identifying MMOSA, LLC and Hutchison

Health, LLC as single member limited liability companies, the amended complaint is devoid of factual allegations regarding these entities. The Worthington Defendants claim MMOSA, LLC did not even exist during the time frame alleged in the amended complaint.

In response, Pacira declines to accept Worthington's unsupported statement absent a sworn affidavit, declaration or any other evidence confirming MMOSA, LLC did not exist as asserted by the Worthington Defendants. Pacira contends it is seeking to hold Nephron and each of the Worthington Defendants collectively liable for their false and/or misleading advertisements.

A complaint cannot rely on "indeterminate assertions against all defendants," a fact that holds true even when some of those defendants are corporate subsidiaries or affiliates of one another. *Qian Yuing v. Ameri-Asia, LLC*, Civil Action No. SAG-23-02684, 2024 WL 1156428, at *2 (D. Md. Mar. 18, 2024)(citing *SD3, LLC v. Black & Decker (U.S.) Inc.*, 801 F.3d 412, 422–23 (4th Cir. 2015)). The amended complaint specifically identifies allegedly wrongful acts taken by Worthington in conjunction with Nephron, but the allegations referring to "Defendants" cannot be read in context as including either MMOSA, LLC or Hutchison Health, LLC. Defendants MMOSA, LLC and Hutchison Health, LLC are dismissed, without prejudice.

2. Whether recipients of information about Dr. Worthington's products were actually deceived or capable of being deceived.

The Worthington Defendants assert (a) Pacira failed to identify a single false statement of fact in any commercial advertisement; (b) Pacira failed to allege any individual or entity in the target audience for its product was actually deceived or was capable of being deceived; and (c) Pacira failed to allege injury in fact and thus lacks standing to proceed with its claim. For the reasons discussed in the court's analysis of Nephron's motion to dismiss, the Worthington Defendants' motion to

dismiss is denied as to this issue.

3. Whether the FDCA precludes Pacira's Lanham Act claims.

The Worthington Defendants argue the court must "step into the FDA's interpretive shoes" and, based upon Pacira's "misapplication of the statutory framework," determine Defendants violated the FDCA. For the reasons discussed in the court's analysis of Nephron's motion to dismiss, the Worthington Defendants' motion to dismiss is denied as to this issue.

IV. CONCLUSION

For the reasons stated, Nephron's motion to dismiss (ECF No. 41) is granted in part and denied in part. The court grants Nephron's motion to dismiss as to (1) Pacira's claims the Website Statements referencing FDA approval and BKK and RKK being produced in a FDA-approved facility are false and misleading, and (2) Pacira's claims the Presentation Statements and other marketing materials referencing FDA approval are false and misleading. Nephron's motion to dismiss is denied in all other respects.

The Worthington Defendants' motion to dismiss (ECF No. 44) also is granted in part and denied in part. The court dismisses Defendants MMOSA, LLC and Hutchinson Health, LLC without prejudice. These Defendants are dismissed because the amended complaint is devoid of factual allegations regarding these entities. Worthington's motion to dismiss is denied in all other respects.

IT IS SO ORDERED.

s/ Cameron McGowan Currie
CAMERON MCGOWAN CURRIE
SENIOR UNITED STATES DISTRICT JUDGE

Columbia, South Carolina
July 15, 2024